UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,906	12/21/2005	Miroslav Patek	281642US0XPCT	1503
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET			EXAMINER	
			DESAI, ANAND U	
ALEXANDRIA, VA 22314			ART UNIT	PAPER NUMBER
			1656	
			NOTIFICATION DATE	DELIVERY MODE
			07/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com oblonpat@oblon.com jgardner@oblon.com

	Application No.	Applicant(s)				
	10/561,906	PATEK ET AL.				
Office Action Summary	Examiner	Art Unit				
	ANAND U. DESAI	1656				
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 18 Ap	oril 2008					
·— · · · · · · · · · · · · · · · · · ·	<u> </u>					
Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-11</u> is/are pending in the application.						
4a) Of the above claim(s) <u>2, 6(drawn to peptides), 7, and 9</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1,3-6,8 and 10</u> is/are rejected.						
7) Claim(s) 11 is/are objected to.						
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9)⊠ The specification is objected to by the Examine	r .					
10)⊠ The drawing(s) filed on <u>21 January 2005</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
A						
Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date.						
3) ☑ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 20051221. 5) ☑ Notice of Informal Patent Application 6) ☑ Other:						
Paper No(s)/Mail Date <u>20051221</u> . 6)						

Art Unit: 1656

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1, 3-5, 8, 10, and 11, drawn to an isolated nucleic acid, a plasmid, vector, micro-organisms, and a method of preparing a polypeptide in the reply filed on April 18, 2008 is acknowledged. The traversal is on the ground(s) that a search of all the claims would not constitute a serious burden on the Office. This is not found persuasive because the inventions lack the same or corresponding special technical feature, because Kopecky et al. describe an isolated nucleic acid sequence that encodes an acetohydroxy acid synthase (see paragraph 3 of Restriction/Election office action mailed March 19, 2008). Therefore, the technical feature does not define a contribution over the prior art and the groups are drawn to different chemical structures.

Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I does not necessarily encode a polypeptide of group II. For example, the nucleic acid molecule of claim 1(c) is complementary to the coding sequence, and therefore would not encode the polypeptide of group II.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. In cases such as this one where descriptive sequence information is provided, the

Art Unit: 1656

sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the polypeptide claims include polypeptides having 70% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search of the nucleic acid molecules of claim 1(g) would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group II. As such, it would be burdensome to search the inventions of groups I and II together.

The requirement is still deemed proper and is therefore made FINAL.

- 2. However, upon review of claim 6 it appears to be partially drawn to a nucleic acid, therefore claim 6 drawn to the nucleic acid will be examined along with the elected invention. Claims 2, 6 (drawn to polypeptides), 7, and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 18, 2008.
- 3. Claims 1, 3-5, 6 (drawn to nucleic acid sequence), 8, 10, and 11 are currently under examination.

Art Unit: 1656

Priority

4. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The priority date is June 26, 2003.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on December 21, 2005 is being considered by the examiner. The EP 0 436 886 document is crossed out because no translation has been provided for the German document.

Specification

- 6. The disclosure is objected to because of the following informalities:
- 7. There is no brief description of the drawings section for Figures 1 and 2.
- 8. On page 19, the table discloses nucleic acid sequences greater than 4 nucleotides in length and is lacking a corresponding SEQ ID NO identifier. Applicant is referred to MPEP 1.821-1.825.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e.,

Art Unit: 1656

results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex

parte Dunki, 153 USPQ 678 (Bd.App. 1967) and Clinical Products, Ltd. v. Brenner, 255 F.

Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 12. Claims 8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite
- for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention.

13. Claim 8 provides for the use of the nucleic acid sequences, but, since the claim does not

set forth any steps involved in the method/process, it is unclear what method/process applicant is

intending to encompass. A claim is indefinite where it merely recites a use without any active,

positive steps delimiting how this use is actually practiced.

14. In claim 10, it is unclear if the plasmid has been deposited or just the transformed

microorganism has been deposited.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1656

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 16. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kopecky et al. (Previously cited in office action mailed 2/7/2008).
- 17. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Livshits et al. (US 2002/0037562 A1).

Livshits et al. disclose an isolated nucleic acid and transformed bacterium that encodes acetohydroxy acid synthase, which is free from inhibition by L-valine. Livshits et al. disclose DNA coding for a small subunit of actohydroxy acid synthase isozyme III originating from Escherichia coli which has a mutation to replace an amino acid, residue corresponding to serine residue at the amino acid number 17 with another amino acid residue in SEQ ID NO: 2, or both of a mutation to replace an amino acid residue corresponding to serine residue at the amino acid number 17 and a mutation to replace an amino acid residue corresponding to glycine residue at the amino acid number 14 with another amino acid residue in SEQ ID NO: 2 (see claim 1). The DNA would hybridize with the isolated nucleic acid currently claimed.

18. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Nakagawa et al. (US 2002/0197605 A1).

Art Unit: 1656

Nakagawa et al. disclose an isolated nucleic acid that can hybridize with the nucleic acid identified as SEQ ID NO: 1, a vector comprising the nucleic acid, and a transformed host cell comprising the isolated nucleic acid (see claims 7-13 and sequence alignment below).

```
RESULT 3
US-09-738-626-1
; Sequence 1, Application US/09738626
; Publication No. US20020197605A1
; GENERAL INFORMATION:
; APPLICANT: NAKAGAWA, SATOSHI
; APPLICANT: MIZOGUCHI, HIROSHI
; APPLICANT: ANDO, SEIKO
; APPLICANT: HAYASHI, MIKIRO
  APPLICANT: OCHIAI, KEIKO APPLICANT: YOKOI, HARUHIKO
; APPLICANT: TATEISHI, NAOKO
; APPLICANT: SENOH, AKIHIRO
; APPLICANT: IKEDA, MASATO
 APPLICANT: OZAKI, AKIO
 TITLE OF INVENTION: NOVEL POLYNUCLEOTIDES
  FILE REFERENCE: 249-125
  CURRENT APPLICATION NUMBER: US/09/738,626
  CURRENT FILING DATE: 2000-12-18
  PRIOR APPLICATION NUMBER: JP 99/377484
 PRIOR FILING DATE: 1999-12-16
 PRIOR APPLICATION NUMBER: JP 00/159162
 PRIOR FILING DATE: 2000-04-07
  PRIOR APPLICATION NUMBER: JP 00/280988
  PRIOR FILING DATE: 2000-08-03
; NUMBER OF SEQ ID NOS: 7059
 SOFTWARE: PatentIn ver. 3.0
; SEQ ID NO 1
   LENGTH: 3309400
   TYPE: DNA
   ORGANISM: Corynebacterium glutamicum
US-09-738-626-1
 Query Match
                       96.9%; Score 503; DB 3; Length 3309400;
 Best Local Similarity 98.1%; Pred. No. 8.2e-151;
 Matches 509; Conservative 0; Mismatches 10; Indels
                                                           0; Gaps
0;
           1 ATGGTCAATTCTGACGTCACCCGCCACATCCTGTCCGTACTCGTTCAGGACGTAGACGAT 60
QУ
            Db
     1340025 ATGGCTAATTCTGACGTCACCCGCCACATCCTGTCCGTACTCGTTCAGGACGTAGACGGA
1340084
QУ
         61 GACTTTTCCCGCGTATCAGGTATGTTCACCCGACGCGCATTCAACCTCGTGTCCCTCGTG 120
```

Art Unit: 1656



Claim Objections

- 19. Claim 11 is objected to because of the following informalities:
- 20. In claim 11, suggest, An isolated microorganism of strain *Corynebacterium glutamicum*, deposited at the Deutsche Sammlung fur Mikroorganismen und Zellkulturen GmbH, Mascheroder Weg 1b, D-38124 Braunschweig, under the accession number DSM15652, DSM15561 or DSM15650.

Appropriate correction is required.

Art Unit: 1656

Conclusion

21. Claim 11 is objected

22. Claims 1, 3-6, 8, and 10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

July 7, 2008

/Anand U Desai, Ph.D./
Patent Examiner, Art Unit 1656